



#### Annual General Meeting 2015

Sydney 9 November 2015

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#### **Forward-Looking Statements**

This Presentation contains certain statements which constitute forward-looking statements or information ("forwardlooking statements"). These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the general economic and industry conditions in Australia and globally and the operations of the Company. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the Company believes the expectations and assumptions reflected in the forward-looking statements are reasonable, as of the date hereof, undue reliance should not be placed on the forward-looking statements as the Company can give no assurances that they will prove correct and because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risks associated with biotechnology companies, regenerative medicine and associated life science companies; delays or changes in plans; specific risks associated with the regulatory approvals for or applying to the Company's products; commercialisation of the Company's products and research and development of the Company's products; ability to execute production sharing contracts, ability to meet work commitments, ability to meet the capital expenditures; risks associated with stock market volatility and the ability of the Company to continue as a going concern. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by securities laws.

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### Agenda



- Competitive Strengths
- Key Achievements for FY15
- Key Achievements to Date for FY16
- Product Pipeline and Overview
  - Technology Overview
  - FY15 Achievements
  - FY16 Outlook
- IP Update
- Financial Results
- FY16 Milestones

### **Competitive Strengths**



Multiple technology platforms based on allogeneic off-the-shelf stem cells and immuno-oncology

Diversified portfolio of clinical stage products for human and animal health markets – focus on musculoskeletal and oncology

Scalable technology platforms

Strategic and growing intellectual property portfolio covering products, uses and manufacturing

Culture of innovation and collaborations across technology R&D, product and clinical development and commercialisation

Experienced management team

### **Key Achievements for FY15**



#### Progress on clinical programs

- ✓ ethics approval for first-in-human trials for:
  - Progenza our allogeneic off-the-shelf stem cell therapy for osteoarthritis
  - RGSH4K autologous cancer vaccine

#### Scalable technology

✓ demonstrated capacity to produce millions of doses of Progenza from a single donor

#### Progress on partnering and licensing discussions

- ✓ progress on partnering discussions:
  - for global sales and marketing of CryoShot Canine allogeneic off-the-shelf stem cell therapy for osteoarthritis
  - for manufacturing and clinical development of Progenza in Japan

#### Substantial increase in IP portfolio

- ✓ 10 new granted patents 1<sup>st</sup> US granted patent
- exclusive licence over oncology immunotherapy technology developed at Kolling Institute for human applications

# Key Achievements to Date for FY16



#### First patients safely dosed in clinical programs

- ✓ first patient safely dosed in Progenza stem cell trial for osteoarthritis August '15
- ✓ first patient safely dosed in RGSH4K cancer vaccine trial Oct '15

#### Partnering update

- partnered with top 5 global animal health company for CryoShot Canine development and commercialisation – Nov '15
- ✓ U Penn pre-pivotal CryoShot trial commenced Nov '15
- partner discussions continue for licensing, manufacture and clinical development of Progenza in Japan

#### R&D tax

✓ received \$3.4m R&D tax rebate for FY15 – Oct '15

# **Product Pipeline and Overview**





# Human Health Pipeline



Product	Indication	Preclinical	Manufacturing	Phase 1	Phase 2	Phase 3	Marketed	Market Size
Progenza	Osteoarthritis	Alloge	eneic adipose MS	Cs				U\$\$12b
RGSH4K	Solid Tumours	Autolo	ogous tumour vac	cine				US\$33b

Allogeneic cells - cells from a donor Autologous cells - patient's own cells

### Stem Cell technology platform



- Our allogeneic stem cell technology platform allows for the scalable production of offthe-shelf cell products for other potential therapeutic uses
- Technology underpins both the Progenza and CryoShot product platforms
- Mesenchymal stem cells (MSCs) are sourced from the adipose (fat) tissue of a healthy donor
- MSCs are expanded using proprietary technology demonstrated capacity to produce millions of doses from 1 donor
- Progenza MSCs are cryopreserved in cell secretions to optimise viability and functionality



#### Secretions - drivers of therapeutic effect \*rege

- MSCs are found in adipose tissue in much greater numbers than other tissue types e.g. bone marrow, blood
- MSCs can differentiate into other cell types
- MSCs respond to signals associated with tissue damage
- MSCs have immune privileges
- MSCs secrete a diverse variety of bioactive factors including cytokines, and growth factors that respond to the local environment and are responsible for reducing inflammation, promoting tissue repair and reducing scarring
- Secretions are the drivers of MSCs therapeutic effect



### **Progenza FY15 Achievements**



- Successful completion of preclinical study demonstrating that Progenza prevented cartilage degeneration
- Successful production of Progenza for trial showing capacity to manufacture millions of doses from single donor
- Ethics approval for first-in-human trial 'STEP' Safety, Tolerability, Efficacy of Progenza
- ✓ Safe treatment of the first patient in STEP trial
- Progress with engagement of potential Japanese partners for development, manufacture and commercialisation of Progenza in Japan - take advantage of new regenerative medicine laws in Japan passed in November '14



#### **Progenza – Positive Preclinical Results**

- No Progenza-related systemic or local toxicities or dose related adverse effects were noted with intra-articular (IA) administration
- Significant reduction in cartilage degeneration scores with target dose in the middle load bearing femur zone (zone 2)
- Total degeneration scores in Progenza treated knees at 4 weeks showed no further progression of OA compared to 21 day pre-treatment control group



#### **Cartilage Degeneration Scores- Lateral Femur**

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### Progenza FY16 Outlook





- Complete Phase 1 enrolment in STEP Trial
- Review blinded safety data
- Seek Japanese partner for manufacture, development and commercialisation in Japan
- Procure donor adipose tissue for Phase 2 and manufacture master seed bank
- Commence PMDA (Japanese regulator)
  consultations
- Investigate partnering opportunities in US and EU

### Human Cancer Vaccine – RGSH4K

#### **FY15 Achievements**

- Secured exclusive global rights for cancer vaccine developed at Kolling Institute of Medical Research
- Ethics approval to commence first-in-human
  'ACTIVATE' clinical trial obtained in May '15
- ✓ ACTIVATE trial open for recruitment
- Ethics approved tumour bank receiving patient samples to support vaccine manufacture

#### FY16 Outlook

- First patient dosed safely Nov '15 trial open for enrollment
- Complete enrollment in the ACTIVATE trial
- Assess emerging study data to:
  - Investigate vaccine safety, and
  - Identify a biologically active dose for further studies



**ereae** 

### **Animal Health Pipeline**





Allogeneic cells - cells from a donor Autologous cells - patient's own cells

### CryoShot



#### **FY15 Achievements**

- Local efficacy trial leads to new potential IP for optimising success of treatment
- Advanced discussions with potential marketing partners for CryoShot Canine
  - Led to signed collaboration in Nov'15 with top 5 animal health company
- Completed preparation for pre-pivotal US trial with U Penn for CryoShot Canine for OA

#### FY16 Outlook

- Commenced pre-pivotal trial at U Penn to de-risk FDA trial – Nov'15
- Sign off on pivotal trial design, product characterisation and manufacture for FDA



### **Kvax – Canine Cancer Vaccine**

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#### **FY15 Achievements**

- Clinical trial for osteosarcoma with Dr Bergman of VCA, largest US vet services group, fully recruited
- 1<sup>st</sup> dog commercially treated outside of the trial in the US
- ✓ >100 dogs treated in Australia

#### FY16 Outlook

- Data readout from osteosarcoma trial
- Commence clinical trial for Kvax for canine lymphoma
- Engage with potential marketing
  partners



# Patent Portfolio Update





### Patent Portfolio Update



- 14 patent families underpinning product portfolio
- 8 patents granted in Australia
- 2 patents granted in NZ
- 1<sup>st</sup> patent granted in USA
- 2 new families
  - Enhanced cell therapies Progenza & CryoShot
  - Manufacture of cells Progenza

### Patent Portfolio – Granted Patents



Austra	alian Granted Patents			
Patent No.	Title	Filing Date	Status	
2013203165	Pharmaceutical compositions and topical use thereof	2013-04-09	GRANTED	
2013203164	Therapeutics for skin conditions	2013-04-09	GRANTED	
2013203072	Therapeutic methods and compositions comprising cells and secretions	2013-04-09	GRANTED	
2012229890	Pharmaceutical compositions and topical use thereof	2012-03-15	GRANTED	
2011247866	Allogeneic therapeutic methods using adipose tissue- derived cell suspensions	2011-11-08	GRANTED	
2009284700	Autologous therapeutic methods using adipose tissue- derived cell suspensions	2009-08-20	GRANTED	
2013204930	Therapeutics using multiple injections of cells	2013-04-12	GRANTED	
2011342382	Arthroscopy method	2011-12-19	GRANTED	
US Gra	anted Patent			
9,062,288	Therapeutic methods using adipose tissue-derived cell suspensions comprising adipocytes	2009-08-20	GRANTED	
NZ Granted Patents				
591626	Therapeutic methods using adipose tissue-derived cell suspensions comprising adipocytes	2009-08-20	GRANTED	
612473	Arthroscopy method	2011-12-19	GRANTED	

### FY15 Financial Results Overview





### **FY15 Financial Results Overview**



S'000's	2015	2014	Change
Revenue	2,061	2,095	(34)
Cost of Sales	(915)	(621)	294
Gross Profit	1,146	1,473	(327)
Other income	3,498	3,868	(370)
R&D expenses	(4,945)	(5,759)	814
Selling expenses	(1,678)	(2,253)	575
Occupancy expenses	(757)	(628)	(129)
Corporate expenses	(3,815)	(3,875)	60
Finance Expenses	(56)	(349)	293
Loss for year	(6,607)	(7,523)	916
Non-recurring expenses	1,631	295	1,336
Underlying loss for year	(4,976)	(7,228)	2,252

- Expenditure focused on R&D production and clinical trials
- R&D expenses reduced as manufacture for Progenza clinical trial completed
- Expenditure reduction following strategic review of HiQCell business

### **Operating Cash Burn**



	\$'000's
Cash at 30 June	3,013
R&D Tax Incentive	3,418
Cash available	6,431
Quarterly cash burn	1,700+
Cash available	3+ quarters

- Cash Burn for past 2 quarters (ex one-off costs) was \$1.7m
- Slight increase anticipated due to execution of clinical trials
- R&D tax incentive of \$3.4m received mid October '15

# **Upcoming Milestones**



Product or Program	Anticipated Milestone	Timing by Calendar Year
Progenza	Cells and secretions patent	Q4'15
Stem Cell Technology Platform	Next generation cell technology	Q4'15
Куах	Commencement of canine lymphosarcoma trial	Q4'15
Progenza	Review of safety data on cohort 1 of STEP trial	Q4'15
Progenza	Secure manufacturing and development partner for Japan	Q1'16
Progenza	Commence enrollment of cohort 2 of STEP trial	Q1'16
Kvax	Data report from canine osteosarcoma trial	Q1'16
Cell secretions cream	Complete stability and clinical testing	H1'16
CryoShot Canine	Compete enrollment in U Penn trial	H1'16
RGSH4K	Complete enrollment in ACTIVATE trial	Q3'16
CryoShot Canine	Data report from U Penn trial	Q3'16

# Questions





# Proxy Snapshot as at 3pm 07/11/2015



• For	Open	Against

- Resolution 1
- **REMUNERATION REPORT** 12,140,896 653,955 912,880
- Resolution 2
- FOR RE-ELECTION OF
- **DR GLEN RICHARDS** 29,206,038 7,907,863 123,676
- Resolution 3
- LISTING RULE 7.1A 28,220,587 7,907,863 772,035